

Application No. 10/616,481  
Amendment "A" and Response dated November 23, 2005  
Reply to Office Action mailed November 1, 2005

### AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

#### Listing of Claims:

1. (Currently Amended) An article of manufacture for use in treating a person's teeth and/or gingiva, comprising:

a substantially solid and coherent medicament composition having a tray-like configuration comprising a front side wall, a rear side wall, and a trough between said front and rear side walls,

said medicament composition having a rigidity so as to maintain itself in the tray-like configuration absent external support,

said medicament composition having increased adhesiveness to teeth and/or gingiva when moistened by saliva or water,

said medicament composition comprising:

at least one medicament; and

at least one tissue adhesion agent that forms a substantially solid matrix within which said medicament is dispersed and that at least partially contributes to said increased adhesiveness to teeth and/or gingiva when said medicament composition is moistened by saliva or water.

2. (Original) An article of manufacture as defined in claim 1, said medicament composition being initially horseshoe shaped prior to use so that said medicament composition at least approximately conforms to a person's dental arch with minimal longitudinal shaping.

3. (Original) An article of manufacture as defined in claim 1, said medicament composition initially having a longitudinal curvature that is less than the curvature of a person's dental arch prior to use so that additional longitudinal curving of said medicament composition is required when said medicament composition is placed over a person's teeth and/or gingiva.

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4. (Original) An article of manufacture as defined in claim 1, said medicament composition initially having a substantially straight longitudinal profile prior to use so that longitudinal curving of said medicament composition is required when said medicament composition is placed over a person's teeth and/or gingiva.

5. (Original) An article of manufacture as defined in claim 1, at least a portion of said trough having an approximate U-shaped cross section.

6. (Original) An article of manufacture as defined in claim 1, at least a portion of said trough having an approximate V-shaped cross section.

7. (Original) An article of manufacture as defined in claim 1, at least a portion of said trough having an approximate L-shaped cross section.

8. (Original) An article of manufacture as defined in claim 1, at least a portion of said trough having approximately a rectangular or trapezoidal cross section.

9. (Original) An article of manufacture as defined in claim 1, said medicament comprising at least one antimicrobial agent.

10. (Original) An article of manufacture as defined in claim 9, said antimicrobial agent comprising at least one of chlorhexidine gluconate, cetylpyridinium chloride, phenol, minocycline, tetracycline, doxycycline, penicillin, clindamycin, ciprofloxacin, metronidazole, or tricolsan.

11. (Original) An article of manufacture as defined in claim 1, said medicament comprising at least one remineralizing agent.

12. (Currently Amended) An article of manufacture as defined in claim 11, said remineralizing agent comprising at least one of a fluoride salt, sodium fluoride, sodium monofluorophosphate, stannous fluoride, and or calcium phosphate.

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13. (Original) An article of manufacture as defined in claim 1, said medicament comprising at least one anti-tartar agent.

14. (Currently Amended) An article of manufacture as defined in claim 13, said anti-tartar agent comprising at least one of pyrophosphate, polypyrophosphate, polyvinyl methyl ether malic acid, sodium hexametal phosphate, alkali metal phosphate, or calcium lactate ~~and triethanol~~.

15. (Currently Amended) An article of manufacture as defined in claim 1, said medicament comprising at least one of an anticalculus or antiplaque agent.

16. (Currently Amended) An article of manufacture as defined in claim 15, said anticalculus or antiplaque agent comprising at least one of 8-hydroxyquinoline sulfate, dicitrate cyclic ester, ~~and~~ or zinc citrate.

17. (Original) An article of manufacture as defined in claim 1, said medicament having a concentration in a range of about 0.01% to about 50% by weight of said medicament composition.

18. (Original) An article of manufacture as defined in claim 1, said medicament having a concentration in a range of about 0.5% to about 25% by weight of said medicament composition.

19. (Original) An article of manufacture as defined in claim 1, said medicament having a concentration in a range of about 0.1% to about 10% by weight of said medicament composition.

20. (Original) An article of manufacture as defined in claim 1, said tissue adhesion agent comprising polyvinyl pyrrolidone.

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21. (Original) An article of manufacture as defined in claim 1, said tissue adhesion agent comprising at least one of carboxypolymethylene, polyethylene oxide, polyacrylic acid, copolymer of polyacrylic acid, polyacrylate, polyacrylamide, copolymer of polyacrylic acid and polyacrylamide, PVP-vinyl acetate copolymer, carboxymethylcellulose, carboxypropylcellulose, polysaccharide gum, or protein.

22. (Original) An article of manufacture as defined in claim 1, said tissue adhesion agent having a concentration in a range of about 10% to about 90% by weight of said medicament composition.

23. (Original) An article of manufacture as defined in claim 1, said tissue adhesion agent having a concentration in a range of about 20% to about 80% by weight of said medicament composition.

24. (Original) An article of manufacture as defined in claim 1, said tissue adhesion agent having a concentration in a range of about 40% to about 75% by weight of said medicament composition.

25. (Original) An article of manufacture as defined in claim 1, said medicament composition further comprising at least one humectant.

26. (Original) An article of manufacture as defined in claim 1, wherein said medicament composition is sized and configured so as to fit over at least a portion of a person's upper dental arch.

27. (Original) An article of manufacture as defined in claim 1, wherein said medicament composition is sized and configured so as to fit over at least a portion of a person's lower dental arch.

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28. (Original) An article of manufacture as defined in claim 1, wherein said medicament composition has a cross-sectional thickness in a range of about 0.1 mm to about 0.5 mm.

29. (Original) An article of manufacture as defined in claim 1, wherein said medicament composition has a cross-sectional thickness in a range of about 0.5 mm to about 2 mm.

30. (Original) An article of manufacture as defined in claim 1, wherein said medicament composition has a cross-sectional thickness in a range of about 2 mm to about 3 mm.

31. (Original) An article of manufacture as defined in claim 1, wherein said medicament composition is contained within a sealed package prior to use.

32. (Original) An article of manufacture as defined in claim 1, further comprising a barrier layer comprising a moisture-resistant material adjacent to an outer surface of said medicament composition that protects the medicament composition from saliva or moisture when in use.

33. (Original) An article of manufacture as defined in claim 32, said barrier layer being flexible so that it will readily conform to the shape of a person's teeth and/or gingiva when in use.

34. (Original) An article of manufacture as defined in claim 32, said barrier layer comprising at least one polyolefin.

35. (Original) An article of manufacture as defined in claim 34, said polyolefin comprising at least one of polyethylene, high density polyethylene, low density polyethylene, ultra-low density polyethylene, polypropylene, or polytetrafluoroethylene.

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36. (Original) An article of manufacture as defined in claim 34, said barrier layer comprising at least one of wax, metal foil, paraffin, ethylene-vinyl acetate copolymer, ethylene-vinyl alcohol copolymer, polycaprolactone, polyester, polycarbonate, polyurethane, polyamide, or polyesteramide.

37. (Original) An article of manufacture as defined in claim 1, said medicament composition further comprising at least one dental bleaching agent.

38. (Original) An article of manufacture as defined in claim 37, said dental bleaching agent having a concentration in a range of about 5% to about 80% by weight of said medicament composition.

39. (Original) An article of manufacture as defined in claim 37, said dental bleaching agent having a concentration in a range of about 10% to about 60% by weight of said medicament composition.

40. (Original) An article of manufacture as defined in claim 37, said dental bleaching agent having a concentration in a range of about 20% to about 50% by weight of said medicament composition.

41. (Original) An article of manufacture as defined in claim 1, said medicament composition further comprising at least one dental desensitizing agent.

42. (Currently Amended) A kit for use in medicating a person's teeth and/or gingiva comprising a plurality of substantially solid medicament compositions having a tray-like shape configuration according to claim 1.

43. (Currently Amended) A method for medicating a person's teeth and/or gingiva comprising obtaining a medicament composition according to claim 1 and then placing said medicament composition over at least a portion of the person's teeth and/or gingiva for a desired time period.

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44. (Currently Amended) A method for medicating a person's teeth and/or gingiva as defined in claim 43, further comprising placing a barrier layer adjacent to an outer surface of said medicament composition.

45. (Currently Amended) An article of manufacture comprising a treatment device for use in treating a person's teeth and/or gingiva, said treatment device comprising:

a barrier layer comprising a moisture-resistant material in the shape of a dental tray comprising a front side wall, a rear side wall, and a trough between said front and rear side walls; and

a medicament layer within said trough comprising a substantially solid medicament composition having a first surface adjacent to said barrier layer and a second surface that has increased adhesiveness to teeth and/or gingiva when moistened by saliva or water, said medicament layer being in the shape of a dental tray and having a rigidity so as to at least partially contribute to maintaining said treatment device in the shape of a dental tray prior to placing said treatment device over a person's teeth and/or gingiva, said medicament composition comprising:

at least one medicament; and

at least one tissue adhesion agent that forms a substantially solid matrix within which said medicament is dispersed and that at least partially contributes to said increased adhesiveness to teeth and/or ~~gingival~~ gingiva when said medicament composition is moistened by saliva or water.

46. (Original) An article of manufacture as defined in claim 45, at least a portion of said trough having a cross section that is approximately U-shaped, V-shaped, L-shaped, rectangular, or trapezoidal.

47. (Original) An article of manufacture as defined in claim 45, said barrier layer being flexible so that it will readily conform to the shape of a person's teeth and/or gingiva when in use.

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48. (Original) An article of manufacture as defined in claim 45, said barrier layer comprising at least one polyolefin.

49. (Original) An article of manufacture as defined in claim 48, said polyolefin comprising at least one of polyethylene, high density polyethylene, low density polyethylene, ultra-low density polyethylene, polypropylene, or polytetrafluoroethylene.

50. (Original) An article of manufacture as defined in claim 45, said barrier layer comprising at least one of wax, metal foil, paraffin, ethylene-vinyl acetate copolymer, ethylene-vinyl alcohol copolymer, polycaprolactone, polyester, polycarbonate, polyurethane, polyamide, or polycesteramide.

51. (Original) An article of manufacture as defined in claim 45, said barrier layer having a rigidity so as to at least partially contribute to maintaining said medicament device in the shape of a dental tray prior to placing said medicament device over a person's teeth and/or gingiva.

52. (Original) An article of manufacture as defined in claim 45, said barrier layer being initially horseshoe shaped prior to use so that said medicament device at least approximately conforms to a person's dental arch with minimal longitudinal shaping.

53. (Original) An article of manufacture as defined in claim 45, said barrier layer initially having a longitudinal curvature that is less than the curvature of a person's dental arch prior to use so that additional longitudinal curving of said medicament device is required when said medicament device is placed over a person's teeth and/or gingiva.

54. (Original) An article of manufacture as defined in claim 45, said barrier layer initially having a substantially straight longitudinal profile prior to use so that longitudinal curving of said medicament device is required when said medicament device is placed over a person's teeth and/or gingiva.



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55. (Original) An article of manufacture as defined in claim 45, said barrier layer comprising a customized dental tray.

56. (Original) An article of manufacture as defined in claim 45, said medicament layer comprising a single coherent mass in the shape of a dental tray comprising a front side wall, a rear side wall, and a trough between said front and rear side walls.

57. (Cancelled)

58. (Original) An article of manufacture as defined in claim 45, said medicament comprising at least one member selected from chlorhexidine gluconate, cetylpyridinium chloride, phenol, minocycline, tetracycline, doxycycline, penicillin, clindamycin, ciprofloxacin, metronidazole, or tricolsan.

59. (Original) An article of manufacture as defined in claim 45, at least a portion of said tissue adhesion agent comprising polyvinyl pyrrolidone.

60. (Currently Amended) A kit for use in ~~medicament~~ medicating a person's teeth and/or gingiva comprising a plurality of treatment devices according to claim 45.

61. (Currently Amended) A method for medicating a person's teeth and/or gingiva comprising obtaining a treatment device according to claim 45 and then placing said treatment device over at least a portion of the person's teeth and/or gingiva for a desired time period.

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62. (Original) A method of manufacturing an article of manufacture comprising a substantially solid and coherent medicament composition, the method comprising:

mixing together a medicament, a tissue adhesion agent and a solvent to form an intermediate flowable composition; and

removing at least a portion of said solvent from said intermediate flowable composition so as to form said substantially solid and coherent medicament composition,

said medicament composition having a tray-like configuration comprising a front side wall, a rear side wall, and a trough between said front and rear side walls.

63. (Original) A method of manufacturing an article of manufacture as defined in claim 62, further comprising forming a barrier layer adjacent to said medicament composition.

64. (Original) A method of manufacturing an article of manufacture as defined in claim 63, wherein said barrier layer comprises a dental tray.

65. (Original) A method of manufacturing an article of manufacture as defined in claim 64, said method comprising first placing said intermediate flowable composition adjacent to said dental tray prior and then removing at least a portion of said solvent from said intermediate flowable composition to form said substantially solid and coherent medicament composition.

66. (Original) A method of manufacturing an article of manufacture as defined in claim 64, said method comprising first forming said medicament composition having a tray-like configuration and then placing it inside a trough within said dental tray.

67. (Original) A method of manufacturing an article of manufacture as defined in claim 63, said method comprising applying an initially flowable material adjacent to said medicament composition and allowing the initially flowable material to solidify into a solid barrier layer.

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68. (Currently Amended) A method of manufacturing an article of manufacture as defined in claim 63, said method comprising first placing said intermediate flowable composition adjacent to a polymeric sheet comprising said barrier layer ~~dental tray~~, removing at least a portion of said solvent from said intermediate flowable composition to form a substantially solid and coherent medicament composition, and shaping the said medicament composition and barrier layer into a the tray-like configuration.

69. (New) A method of manufacturing an article of manufacture as defined in claim 63, wherein said barrier layer comprises a single layer of a water-resistant polymeric material.